510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

k123559

B. Purpose for Submission:

Modification of previously cleared device to add wireless data management feature, earphone jack and rearrangement of buttons on device.

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Quantitative, glucose oxidase

E. Applicant:

Biotest Medical Corporation

F. Proprietary and Established Names:

SOLUSmobile Blood Glucose Management System, Model 6134

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1345 Glucose Test System
   21 CFR 862.1660, Quality Control Material (assayed and unassayed)

2. Classification:

   Class II, Class I

3. Product code:

   NBW - Blood glucose test system, over the counter

   CGA - Glucose oxidase, glucose test system

   JJX – Quality Control Material

4. Panel:

   Clinical Chemistry

H. Intended Use:

1. Intended use(s):

   Refer to indications for use below.

2. Indication(s) for use:

SOLUSmobile Blood Glucose Management System (Model 6134)

The SOLUSmobile Blood Glucose Management System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the forearm. It is intended for use by a single patient with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program, and should not be shared. The SOLUSmobile Blood Glucose Management System is not intended for the diagnosis of or screening for diabetes mellitus, nor for use in neonates. The alternative site testing (forearm) in this system can only be used during steady-state blood glucose conditions. This system contains an audible readout function that provides an audible message of test results for users. The SOLUSmobile Blood Glucose Management System uses cellular data transmission to send test results to a remote central data repository, Telemed-Gluconet.

SOLUSmobile Blood Glucose Test Strips

The SOLUSmobile Blood Glucose Test Strips are to be used with the SOLUSmobile Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood from the finger and the forearm. These test strips are intended for use by a single patient with diabetes mellitus at home and should not be shared. They are not indicated for the diagnosis of or screening for diabetes mellitus, nor for use in neonates. Forearm testing should be done only during steady-state blood glucose conditions.

SOLUSmobile Control Solutions

The SOLUSmobile Control Solutions are for use with the SOLUSMobile Blood Glucose Meter and SOLUSMobile Test Strips to check that the meters and test strips are working together properly and that the test is performing correction. A control test that falls within the acceptable range indicates the user technique is appropriate and the test strip and meter are functioning properly.

3. Special conditions for use statement(s):

   - It is not intended for the diagnosis of or screening for diabetes mellitus
   - Not intended for use on neonates.
   - For *in vitro* diagnostic use only, over-the-counter use, and prescription use.
   - The device should not be used for patients who are dehydrated, in shock, critically ill, or experiencing a hyperglycemic-hyperosmolar state.
   - AST results should not be used for calibration of continuous glucose monitors
   - AST results should not be used in insulin dose calculations

4. Special instrument requirements:

SOLUSmobile Glucose Meter, Model 6134

I. Device Description:

The SOLUSmobile Blood Glucose Management System (Model 6134) starter kit consists of the following components: the SOLUSmobile Glucose Meter (Model 6134), SOLUSmobile blood glucose test strips, User Guide, Quick Start Guide, Log Book, Protective Case, control solution (low), sterile lancets, lancing device, package inserts for test strips, control solution, and lancets/lancing device, battery charger, and charging cable. High and Low levels of control solutions may be purchased separately. The control solutions were previously cleared under k032029. The meter comes with a speaking function with an earphone jack for audible test results, however, this device is not intended for visually impaired users.

J. Substantial Equivalence Information:1. Predicate device name(s):

SOLO V2 Blood Glucose Management System (Model 6131)

2. Predicate 510(k) number(s):

k093764

3. Comparison with predicate:

Item	Predicate Device: SOLO V2 (K093764)	Candidate Device: SOLUSmobile (k123559)
Intended Use	The SOLO V2 Blood Glucose Management system (Model 6131) is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the forearm. It is intended for use by healthcare professionals and people with diabetes mellitus at home and as an aid in Management the effectiveness of a diabetes control program. The SOLO V2 Blood Glucose Management system (Model 6131) is not intended for the diagnosis of or screening for diabetes mellitus, nor for use in neonates.	Same

	The alternative site testing (AST) in this system can only be used during steady-state blood glucose conditions. This system contains speaking function that provides an audible message of test results for users with low vision.	
Enzyme	Glucose oxidase(Aspergillus niger)	Same
Temperature compensation	Automatic compensation with built-in thermister	Same
Sample volume	0.7 uL	Same
Measurement Range	20 - 600 mg/dL	Same
Reaction time	6 seconds	Same
Operating condition	10 ℃to 40 ℃, relative humidity 20%~80%	Same
Memory feature	500 measurements with day and time	Same
Day average	7-, 14-, 28-, 60-, 90- day average glucose result	Same
Auto Shut Off	Yes	Same
Alarm	Beeping sound and/or error message in LCD display	Same
Test strip calibration	No code strip is needed. The meter and the test strip should have the same reference number printed on the meter box and on the test strip box and vial. The meter also displays the reference number when inserting the test strip.	Same
Speaking (audible read out) Function	Yes	Yes
Alternative Sites	Forearm	Same
Data download function.	Yes, the meter can	This feature is replaced by

	download the test data to a PC.	automatic wireless data transmission capable of sending the test results over the wireless cellular network to a Central Data Repository at a preset time interval in a day.
Power	Alkaline AAA 1.5 V battery x 2	3.7V/1000mAh rechargeable Li- polymer battery
Size(mm)	100(L)x55(W)x18(H)	119(L)x58.3(W)x20.8(H)
Weight (g)	90 g	115 g

Item	Predicate: SuperCheck 1 Control Solution (k091815)	Candidate: SOLUSmobile Control solution (k123559)
Similarities		
Number of Levels	2	Same
Matrix	Buffer aqueous with glucose, sodium benzoate, viscosity modifier and non-reactive ingredient	Same
Storage Temperature	46 - 86°F (8 - 30°C)	Same
Traceability	Traceable to NIST SRM 917A Clinical Dextrose	Same
Differences		
Nomenclature	Low, High	Level I, Level III

K. Standard/Guidance Document Referenced (if applicable):

1. ISO 11137-1:2006 Sterilization of Health Care Products—Radiation—Part 1: Requirements for Development, Validation, and Routine control of a sterilization process for medical devices
2. IEC/IEN 61010-1: 2001 Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use. General Requirements.
3. IEC/IEN 61010-2-101 Part 2-101: Particular Requirements for in vitro Diagnostic (IVD) Medical Equipment.
4. IEC 61326-2-6:2012 Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements – Part 2-6: Particular Requirements
5. ISO 14971: 2007 Medical Devices—Application of Risk Management to Medical Devices.
6. ISO 15197:2003 In vitro Diagnostic Test Systems – Requirements for Blood-Glucose Monitoring Systems for Self-Testing in Managing diabetes mellitus.
7. BS EN ISO 13640:2002 Stability Testing of in vitro Diagnostic Reagents

L. Test Principle:

The SOLUSmobile Glucose Meter utilizes a glucose oxidase enzyme as the standard dry reagent assay for glucose in whole blood. This enzyme assay, with a redox chemical "mediator" reaction, is used to generate an electrical current proportional to the glucose concentration in the blood sample. The system is designed as an amperometric measurement device using current generated for the redox reaction as the measureable response.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:
Precision previously established in the SOLO V2 Blood Glucose Management system, Model 6131 (k093764) submission.

b. Linearity/assay reportable range:
Linearity previously established in the SOLO V2 Blood Glucose Management system, Model 6131 (k093764) submission.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Stability of the SOLUSmobile Blood Glucose Test Strips was previously established in the SOLO V2 Blood Glucose Management system, Model 6131 (k093764) submission.

Value assignment and stability of the control solutions were previously established under k032029.

d. Detection limit:

The measuring range of the SOLUSmobile Blood Glucose Management System (Model 6134) is 20 to 600 mg/dL. This range was verified by the linearity study (see section M.1.b of this decision summary).

e. Analytical specificity:
Interference study previously established in the SOLO V2 Blood Glucose Management system, Model 6131 (k093764) submission.

Hematocrit Study:
Hematocrit study previously established in the SOLO V2 Blood Glucose Management system, Model 6131 (k093764) submission.

Altitude Study:
The effect of varying altitudes previously established in the SOLO V2 Blood Glucose Management system, Model 6131 (k093764) submission.

Humidity Study:
The effect of humidity previously established in the SOLO V2 Blood Glucose Management system, Model 6131 (k093764) submission.

Temperature Study:
The effect of temperature previously established in the SOLO V2 Blood Glucose Management system, Model 6131 (k093764) submission.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:
Comparison studies were performed with the YSI-2300 reference method. System accuracy, lay-user performance evaluation, and a visually impaired user study was previously performed and established in the SOLO V2 Blood Glucose Management system, Model 6131 (k093764) submission.

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Expected plasma blood glucose values for normal, non-diabetic adults are as follows:

Before eating < 100

mg/dL Two hours after meals < 140
mg/dL

Reference: American Diabetes Association: Diabetes Care, January 2013, volume 36 (suppl. 1) S67-S74.

N. Instrument Name:

SOLUSmobile Glucose Meter, Model 6134

O. System Descriptions:

1. Modes of Operation:

   Each test strip is single use and must be replaced with a new strip for additional readings. The labeling and user guide specify the lancet and the strip are for single use only and instruct the user to discard immediately after use.

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?:
   Yes __X__ or No _____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?:
   Yes __X__ or No _____

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes __X_____ or No _____

3. Specimen Identification:

   There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:

   This device is intended to be used with capillary whole blood from the finger and the forearm (AST) which can be applied directly to the test strip.

5. Calibration:

   No coding. The meter and test strip have the same reference number printed on the meter box and on the test strip box and vial.

6. Quality Control:

   The sponsor provides two levels of controls (Level I and Level III) with this glucose monitoring system. When the test strip is inserted into the meter, each control can be measured by following the instructions for "Running a Control Solution Test" provided in the User Manual for the meter. An acceptable range for each control level is printed on the test strip vial label. The user is instructed to contact a customer assistance line during operational hours or a healthcare provider outside hours of operation if the control results fall outside these
   ranges. Controls values and value ranges are assigned as described in section M.1.c of this decision summary.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

1. Infection Control:

The device system is intended for single-patient use only. Disinfection efficacy studies were performed on the material comprising the meter and lancing device by an outside commercial testing demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, Clorox® Bleach Germicidal Wipes (EPA Reg No: 67619-12). Robustness studies were also performed by the sponsor demonstrating that there was no a change in performance or external materials of the meter and lancing device after 11,000 cleaning and 11,000 disinfection cycles, using Clorox® Bleach Germicidal Wipes to simulate 3 years of use by layusers. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

2. Readability:

A Flesch-Kincaid analysis was conducted and the resulting grade level at which the device labeling is written is as follows:

Labeling	Flesch-Kincaid Grade Level Score
User's Manual	7.8
Test Strip Inserts	7.6

Control Solution Inserts	7.3

3. EMC:

EMC testing was evaluated and certified by MET Laboratories, Inc. and Verification of Compliance certificates provided.

4. Usability Studies:

A cellular functions usability study was performed at three sites using 60 total participants. The purpose of the study was to demonstrate that the intended use population can easily use the new features of this meter (automatic wireless data transmission feature, addition of an airplane mode button, addition of a backlight, addition of an ear phone jack, and a rearrangement of control button). Each participant could read and understand English and the participant ages ranged from 21 to 63. Each participant completed the usability test utilizing only the User's Guide and all participants indicated that the meter was easy to use.

An additional usability study was conducted using 20 participants, ages ranging from 22 – 54,. All of the participants had prior experiences with using a computer. The participants were given a user's guide written in English and were allowed to ask customer service representatives if they had any questions. In this study, the voice level feature was evaluated, along with the earphone jack accessory in which the audible output was evaluated as well. Each user tested the airplane mode feature and at the end of the study each participant completed a questionnaire to evaluate the ease of use of the SOLUSmobile meter. All participants indicated that the meter was easy to use.

5. Data Transmission:

The effectiveness and reliability of the data transmission (manual and automatic) functions were evaluated through memory storage and synchronization testing.

In the memory storage study, the accuracy of transmission of 500 glucose measurements (memory capacity of meter which includes day and time of glucose measurement) from the meter to the central data repository was evaluated on two separate occasions. The results of the memory storage study demonstrated accurate and reliable transmission of every glucose measurement from the meter to the central data repository.

In the synchronization study, the automatic transmission of glucose measurements was evaluated as a part of the cellular functions usability study. Each participant synchronized and transmitted glucose test results, in three replicates, from their meter to the central data repository. The results of the study demonstrated accurate and reliable transmission of every glucose measurement from the meter to the central data repository.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.